

REMARKS/ARGUMENTS

Prior to making remarks and arguments in favor of the patentability of the present application's pending claims, Applicants call to the attention of the Examiner, related co-pending applications 10/857,177 (Attorney Docket No. 021872-002000US) and 10/974,008 (Attorney Docket No. 021872-002010US). These cases are presently in active prosecution before different Examiners. Applicants assume the Examiner has access to the prosecution files of these cases but will provide copies of the relevant prosecution papers if requested.

Claims 19, 21-26, and 28-34 were pending in the application. The pending claims were examined and rejected. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Claim Rejections - 35 U.S.C. §102(b):

Claims 19, 26 and 28 were rejected as allegedly being anticipated by U.S. Publication No. 2002/0111647 to Khairkhahan et al. ("Khairkhahan"). Such rejections are traversed in part and overcome in part as follows.

Khairkhahan fails to disclose each and every element of independent claim 19, the claim from which claims 26 and 28 depend. For instance, Khairkhahan fails to disclose the limitation "*wherein the first expansible member comprises a **single wire** that can be shifted between a straightened contracted configuration and a helical expanded configuration*" (emphasis added), even before amendment. The Examiner interprets proximal spoke 218 of Khairkhahan as the "*single wire*" of claim 19. The occlusion device 10 of Khairkhahan comprises a **plurality** (emphasis added) of proximal spokes 218 ([0066]-[0069]). Also, although proximal spoke portions 218 may be curved radially outward as in Fig. 7, they are not in a "**helical expanded configuration**" (emphasis added). As explained previously in the Amendment of January 29, 2008, one skilled in the art would not consider proximal spoke portions 218 as forming a helix.

Nevertheless, to further expedite prosecution and to more fully claim the invention, independent claim 19 has been amended to recite:

An expandible device for use in a body lumen or tract, the device comprising:

a tubular member having a lumen, a proximal end, and a distal end;

a first expandible member disposed on the distal end of the tubular member, the first expandible member having a contracted configuration and an expanded configuration, wherein the first expandible member consists essentially of a single wire that can be retracted into the lumen of the tubular member to shift the single wire from a completely helical expanded configuration to a straightened contracted configuration;

a first deformable membrane at least partially disposed over the first expandible member in the expanded configuration;

a second expandible member disposed proximal to the first expandible member and on the distal end of the tubular member, the second expandible member having a contracted configuration and an expanded configuration comprising a cylindrical shape,

wherein the first deformable membrane has a spherical shape when the first expandible member is in the expanded configuration.

Support for the amendments can be found from paragraphs 0033-0035, 0078 and Figs. 1 and 2 of the original specification and drawings as filed. By using the phrase "consists essentially of" in place of "comprising", Applicants clarify that there is only one wire and no more. Khairkhan also fails to disclose the added limitation "a single wire that can be retracted into the lumen of the tubular member to shift the single wire from a completely helical expanded configuration to a straightened contracted configuration."

Claim Rejections - 35 U.S.C. §103(a):

Claims 19 and 22-25 were rejected as being allegedly obvious over U.S. Patent No. 5,861,003 to Latson et al. ("Latson") in view of Khairkhahan. Such rejections are traversed as follows.

Latson and Khairkhahan, alone or in combination, fail to disclose each and every element of independent claim 19, from which claims 22-25 depend, even before amendment. For instance, Latson and Khairkhahan both fail to disclose the limitation "*the second expansible member has a **cylindrical shape** when the second expansible member is in the expanded configuration*" (emphasis added). Latson teaches an occlusion bag having a "figure-eight" or dumbbell shape composed of two disc-shaped sacs with the sacs joined at their respective centers (col. 3, ln. 2-9; col. 4, ln. 33-47; Fig. 2). Khairkhahan does not disclose any alternate shape, much less a "*cylindrical shape*", of its disclosed occlusion device.

Furthermore, neither Latson nor Khairkhahan disclose the added limitation "*wherein the first expansible member consists essentially of a single wire that can be retracted into the lumen of the tubular member to shift the single wire from a completely helical expanded configuration to a straightened contracted configuration*" of claim 19 as amended.

Because Latson and Khairkhahan, alone or in combination, fail to disclose each and every element of independent claim 19, *prima facie* obviousness cannot be established. Applicants respectfully request withdrawal of the obviousness rejections of claim 19 and claims 22-25 which depend therefrom.

Claims 19, 21, 29, 30 and 32-34, which depend therefrom, were rejected as allegedly being obvious over U.S. Patent No. 6,071,300 to Brenneman et al. ("Brenneman") in view of U.S. Patent No. 5,061,274 to Kensey ("Kensey"). Such rejections are traversed in part and overcome in part as follows.

Brenneman and Kensey, alone or in combination, fail to disclose each and every element of independent claim 19, from which claim 21 depends, even before amendment. For instance, neither reference discloses the limitation "*the first expansible member comprises a*

single wire", as required by claim 19 before amendment. Contrary to the Examiner's interpretation, locating balloon 50 of Brenneman, which was interpreted as the "*first expansible member*", does not comprise distal end 82 of standard guidewire 78 of Brenneman, which was interpreted as the "*single wire*." Locating balloon 50 and distal end 82 are two separate and distinct components which can be used in lieu of each other (col. 7, ln. 67 - col. 8, ln. 6). Moreover, distal end 82 of standard guidewire 78 cannot be "*shifted between a straightened contracted configuration and a helical expanded configuration*", as required by claim 19 before amendment.

Brenneman and Kensey, alone or in combination, also fail to disclose each and every element of independent claim 29, from which claims 30 and 32-34 depend, even before amendment. For instance, neither reference discloses the step of "*causing a straight wire within the first expansible member to assume a helical configuration such that it expands the expansible member to an expanded configuration comprising a spherical shape*." The only expandable members which Brenneman discloses are compression balloon 42 and locating balloon 50. Both are not expanded by the action of a wire. Instead, both are inflated by the introduction of a fluid (col. 5, ln. 41-51; col. 6, ln. 28-30). Kensey discloses a plug which expands in the presence of a liquid and which can be further expanded to a mushroom-shaped configuration 68 by pulling a proximally extending filament portion 58 (col. 7, ln. 1-17). The means by which the plug of Kensey expands is distinct from the "*causing a straight wire...*" step of claim 29.

Furthermore, neither of the cited references disclose a second expansible member having a "*cylindrical shape*" when in the expanded configuration, a limitation common to claims 19 and 29. While Brenneman may show an expanded compression balloon 42 in Fig. 7, it is not clear that the shape shown of the expanded compression balloon 42 is cylindrical. Kensey discloses a plug that may be expanded to a mushroom-shaped configuration 68, a configuration which does not have a cylindrical shape (col. 7, ln. 1-17; Fig. 8).

Because Latson and Khairkahan, alone or in combination, fail to disclose each and every element of independent claim 19 and of independent claim 29, *prima facie* obviousness cannot be established. Applicants respectfully request withdrawal of the obviousness rejection of claims 19, 21, 29, 30 and 32-34.

It is also noted that independent claim 29 has been amended to clarify the claimed subject matter. The phrase "*in an expanded configuration*" has been removed for clarity. In line 9, the phrase "*expansible member*" has been amended to "first *expansible member*" and "it" has been amended to "the wire." No other limitations and no new matter has been added.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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